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EXAMINER

SORKIN, DAVID L

ART UNIT PAPER NUMBER

1723

DATE MAILED: 02/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,116

Applicant(s)

TEPIC, SLOBODAN

Examiner

David L. Sorkin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 21-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13 and 17-20 is/are rejected.
- 7) ☒ Claim(s) 12 and 14-16 is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1-20, in Paper No. 6 is acknowledged. Applicant states that "the USPTO cannot now properly require restriction" because "'unity' of the claims was implicitly acknowledged during the international phase". However, 37 CFR 1.499 states "If the examiner finds that a national stage application lacks unity of invention under § 1.475, the examiner may in an Office action require the applicant in the response to that action to elect the invention to which the claims shall be restricted." Applicant alleges that claim 21 "depends" from claim 1; however, as explained in the previous office action claim 21 is an improper claim, not a dependent claim. As explained in MPEP 608.01(n)(II), "Any claim which is in dependent form but which is so worded that it, in fact is not, as, for example, it does not include every limitation of the claim on which it depends, will be required to be *canceled* as not being a proper dependent claim; and cancellation of any further claim depending on such a dependent claim will be similarly required" (emphasis in original). The MPEP statement is based upon 37 CFR 1.75(c) and 35 U.S.C. 112, fourth paragraph. 35 U.S.C. 112, fourth paragraph states "a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed." Claim 21 does not met this requirement and therefore is not a dependent claim. While claim 21 includes several references to intended contents of the claimed apparatus, "Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the

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apparatus claim." *Ex parte Thibault*, 164 USPQ 666,667 (Bd. App. 1969). In actuality, the only shared features between claims 1 and 21 are a container having an inlet and outlet and another container. Such is clearly not a "special technical feature" because it is notoriously non-inventive and anticipated by, for example, a funnel and receiving vessel, or a funnel and a quart of motor oil. There is nothing "special" or "specially adapted" about a container having an inlet and outlet and another container.

The requirement is still deemed proper and is therefore made FINAL.

Specification

2. The disclosure should avoid references to specific claim numbers, such as those found in the first paragraph of page 1, because claims may be renumbered, canceled or amended during prosecution.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The scope of claim 3 is unclear due to the phrase "preferably contained within said particles". It is unclear whether the claim requires the benzoyl peroxide to be contained within said particles.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Tepic (US 5,051,482). Claim 20 is a product-by-process claim to a bone cement mixture obtained by the method of claim 1. The method of claim 1 is discussed in detail below regarding section 103; however, as held in *In re Thorpe*, 227 USPQ 964, 966 (Fed Cir. 1985), "[t]he patentability of a product does not depend on its method of production". As discussed below, the sole difference between the method of claim 1 and the method of Tepic ('482) is the use of in external vs. internal vacuum source. There is no reason to believe that the location of the vacuum source in any way affects the bone cement product. All chemical aspects of the prior art and instant bone cements are identical. "When the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not" *In re Spada*, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-11 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tepic (US 5,051,482) in view of WO 97/18031. Regarding claim 1, Tepic ('482) discloses a method of bone cement preparation from a polymeric powder and a liquid

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component, comprising a polymerisable monomer (see abstract), by action of a catalytic system (see abstract), wherein particles of said powder component are packed in a powder container (4,11) with an inlet port (15) and an outlet port (at the bottom of container as seen in Figs. 3-6) and the liquid component is held in a liquid container (12), comprising the steps of completely filling said powder container with said polymeric powder (see Fig. 4; col. 3, lines 47-48); connecting said liquid container to said inlet port (see Fig. 5; col. 2, lines 61-63); and completely flooding a void space between said particles of said powder component with said liquid component, said component flowing from said inlet port in toward said outlet port by action of a vacuum source (see col. 2, lines 66-68 and col. 3, lines 6-8). While the powder container is pre-evacuated, the act of connect a vacuum source to an outlet port is of the container is not explicitly disclosed. WO 97/18031 connecting a vacuum source to an outlet of a container polymeric powder container during a bone cement preparation process (see page 4, lines 30-32; Figs. 3, 4, 6, 8, 9). It is considered that it would have been obvious to one of ordinary skill in the art to have connect a vacuum source to the outlet port of Tepic ('482) because WO 97/18031 explains that such a connection provides the dual benefits of "[r]apid and effective feeding" and "safe handling of the gases that are environmentally harmful and injurious to human health" (see page 3 line 30 to page 4 line 2). Regarding claim 2, Tepic ('482) discloses a method of bone cement preparation from a polymeric powder and a liquid component, comprising a polymerisable monomer (see abstract), by action of a catalytic system (see abstract), wherein particles of said powder component are packed in a powder container (4,11) with an inlet port (15) and

an outlet port (at the bottom of container as seen in Figs. 3-6) and the liquid component is held in a liquid container (12), comprising the steps of packing said powder in said powder container to a fractional porosity of 0.3 to 0.43 (see col. 3, lines 35-39 and 47-48); connecting said liquid container to said inlet port (see Fig. 5; col. 2, lines 61-63); and completely flooding a void space between said particles of said powder component with said liquid component, said component flowing from said inlet port in toward said outlet port by action of a vacuum source (see col. 2, lines 66-68 and col. 3, lines 6-8). While the powder container is pre-evacuated, the act of connect a vacuum source to an outlet port is of the container is not explicitly disclosed. WO 97/18031 connecting a vacuum source to an outlet of a container polymeric powder container during a bone cement preparation process (see page 4, lines 30-32; Figs. 3, 4, 6, 8, 9). It is considered that it would have been obvious to one of ordinary skill in the art to have connect a vacuum source to the outlet port of Tepic ('482) because WO 97/18031 explains that such a connection provides the dual benefits of "[r]apid and effective feeding" and "safe handling of the gases that are environmentally harmful and injurious to human health" (see page 3 line 30 to page 4 line 2). Regarding claim 3, the catalytic system comprises benzoyl peroxide (see col. 2, lines 34-39). Regarding claim 4, WO 97/18031 further teaches an inlet and outlet of the container allowing air and liquid to pas thereby, but not powder (see page 5, line 29, page 6, lines 3-7 and 17-19). Regarding claim 5, the powder container is inflexible and in the form of a syringe (see col. 2, lines 20-24). Regarding claim 6, said powder in said powder containing compartment is packed to a fractional porosity of 0.34 to 0.38 (see col. 3, lines 35-39).

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Regarding claim 7, said powder in said powder containing compartment is packed to a fractional porosity of 0.35 to 0.37 (see col. 3, lines 35-39). Regarding claim 8, the powder component is flooded by said liquid component in 15 to 60 seconds (see col. 3, lines 9-10). Regarding claim 9, the powder component is flooded by said liquid component in 25 to 35 seconds (see col. 3, lines 9-10). Regarding claim 10, WO 97/18031 further teaches controlling flow between a liquid container and an inlet port of a powder container via a valve (see page 7, lines 11-14). Regarding claim 11, draining of excess liquid component and extrusion of the mixed components are disclosed in col. 3, lines 15-25. Although the word "swelling" is not used by Tepic ('482), it is considered that swelling would intrinsically occur in the method of Tepic ('482), because the same powder is being exposed to the same liquid in the prior art and instant application. Regarding claim 17, said polymerizable monomer is methyl-methacrylate (see abstract).

9. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tepic (US 5,051,482) in view of WO 97/18031, as applied to claim 1 above, and further in view of Seaton et al. (US 6,024,480). While Tepic ('482) and WO 97/18031 do not explicitly state that a mesh in the inlet port that prevents particles from passing while allowing particles, Seaton ('480) teaches an inlet port having such a mesh (see col. 8, lines 4-12). It is considered that it would have been obvious to one of ordinary skill in the art to have provided the inlet port with a mesh as taught by Seaton ('480), because Seaton ('480) explains that such a mesh provides the benefit of preventing glass fragments from entering (see col. 8, lines 4-12).

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10. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tepic (US 5,051,482) in view of WO 97/18031, as applied to claim 1 above, and further in view of Lidgren et al. (US 5,328,262). While Tepic ('482) and WO 97/18031 do not discuss specific vacuum pressure values, Lidgren ('262) explains that a vacuum of 85-90% (100-150 mbar) is preferable for making bone cement, which overlaps the claimed ranges (see col. 4, lines 31-32). Therefore, it is considered that it would have used a vacuum pressure in the claimed ranges because this is what Lidgren ('262) explains is preferable for making bone cement (see col. 4, lines 31-32).

Allowable Subject Matter

11. Claim 12 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. This claim is indicated as directed to allowable subject matter, because the prior art does not disclose or fairly teach the draining of liquid being effected by a piston which is contained in a vacuum pump, in combination with the limitations of claims 1 and 11.

12. Claims 14-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The claims are indicated as directed to allowable subject matter because the prior art does not disclose or fairly teach using a gap to block powder particles while allowing air and said liquid to pass, in combination with the limitations of claim 1.

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Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Sorkin whose telephone number is 703-308-1121. The examiner can normally be reached on 8:00 -5:30 Mon.-Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 703-308-0457. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



David Sorkin

February 21, 2003



CHARLES E. COOLEY
PRIMARY EXAMINER